

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR
WARMING PRODUCTS LIABILITY
LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:

All Cases

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE
OPINIONS OF JOHN ABRAHAM, PH.D.**

INTRODUCTION

Plaintiffs moved to exclude the opinions offered by Defendants' expert, John Abraham. Rather than address the many aspects of his opinions and testimony that fall short of the requirements of Fed. R. Evid. 702, 3M spent much of its response on two things: (1) blurring the lines of computational fluid dynamics and expert understanding of how and why to model particle movement in turbulent flow, and (2) repeating its misplaced attacks on Dr. Elghobashi's CFD analysis.

Much of the brief misstates the bases upon which Plaintiffs sought to exclude Abraham's testimony, together with repeated attempts to backfill Abraham's report and reconfigure the relevant field of inquiry. Plaintiffs do not disagree that, in the right case, Abraham is likely qualified to testify about some aspects of heat transfer. But this is not a case about heat transfer. No patient in this case is claiming a burn injury; this case is about infections.

Abraham has offered no authority supporting his assertion that movement of particles is akin to movement of air. He modeled air molecules, which he claims demonstrate airflow, which he uses to diagram streamlines to justify his leap to the desired conclusions on the ultimate issue in this case. Defendants request this Court qualify Abraham as an expert based on nothing more than his say-so, and flies in the face of testimony from other experts offered by the Defendants. A curriculum vitae padded full of presentations and publications in utterly irrelevant areas cannot turn a pumpkin into a horse-drawn chariot. Misquoting conclusions reached by various articles and government agencies as supportive of Abraham's conclusions on the ultimate issue

reveals rotten motives.¹ Experience alone cannot give Abraham free reign to testify about particle movement in turbulent flows without also satisfying the other requirements of Rule 702. Plaintiffs' motion identified additional shortcomings in Abraham's proposed testimony, most of which was not meaningfully addressed by 3M.

Finally, Defendants argue that Plaintiffs' failure to specifically identify certain opinions with which Plaintiffs disagree operates as a tacit adoption of those opinions. That argument is illogical and incorrect. Even if Plaintiffs failed to seek exclusion of evidence, that would not mean Plaintiffs concede the substance of Abraham's proposed testimony. At most it would mean that the evidence meets the requirements of Rule 702. Defendants' many assertions to the contrary should be dismissed out of hand.

Defendants' Response does not squarely address most of the requested bases for exclusion. Those reasons remain unrebutted, and for brevity's sake, will not be reargued here. For the reasons set forth in Plaintiffs Motion and further described below, Plaintiffs' motion to exclude Abraham's opinions should therefore be granted.

¹ See, e.g., Def. Opp. at 6, arguing Abraham's studies, grounded in reliable methodologies, "confirm what numerous healthcare organizations have already concluded: that the Bair Hugger is not capable of causing surgical site infections." (citing the August 30, 2017 FDA letter, which states the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.) The FDA, of course, made no such proclamation about whether or not the Bair Hugger is capable of cause infections. Other articles have in fact, reached the opposite conclusion. The International Consensus overwhelmingly recognized precisely the theoretical risk of infection associated with disturbance of airflow caused by use of forced air warming products. See *Operative Environment, International Consensus of Orthopedic Surgeons*, J ORTHOP RES 32:S60-S80 (2014).

ARGUMENT

I. Abraham is not qualified to offer most of the disclosed opinions.

Abraham equivocated about his qualifications to offer expert testimony about particle movement in turbulent flows early in his deposition.² After additional questioning Abraham himself conceded at his deposition he isn't an expert in particle movement in high-speed flows, or in low-speed flows.³

Faced with that admission, Defense counsel invented something in between, an undefined, middle-speed flow. (Def. Opp. at 5). That attorney argument is not enough. The party offering expert testimony must show by the preponderance of the *evidence* that the expert is qualified. *See Khoury v. Philips Med. Sys.*, 614 F.3d 888, 892 (8th Cir. 2010). Defendants failed to cite to any authority, document, deposition testimony, or other source of *evidence* supporting the existence of such a not-too-fast, not-too-slow rate of particle movement. Moreover, Defendants offered no *evidence* to support the implication that the conditions upon which Abraham seeks to testify are within their new “Goldilocks” particle flow rate.

The Eighth Circuit has “repeatedly upheld the exclusion or reversed the admission of expert design testimony that went beyond the expert’s expertise.” *American Auto. Ins. Co. v. Omega Flex, Inc.*, 783 F. 3d 720, 724-725 (8th Cir. 2015). Expertise in one area does not give an expert free reign to testify about other subject matters. *See Wheeling*

² DX2 (Abraham Dep. 124:6-19).

³ DX2 (Abraham Dep. 246:3-8).

Pitts. Steel v. Beelman River Terminals, 254 F.3d 706, 715 (8th Cir. 2001) (holding district court abused discretion by admitting testimony outside scope of expert's field).

In addition to the lack of evidence to support the existence of a new middle-speed particle flow rate, Defendants make no effort to show how Abraham's experience could meet the "qualification" standard for *any* of the following opinions or conclusions Abraham offered in his expert report outside of his simulation. Specifically, Defendants have not established Abraham's qualifications in infectious disease, epidemiology, surgery, biology, or any other field that might reasonably support a claim of expertise to testify about the risk of periprosthetic joint infection or the efficacy or importance of surgical warming devices.

Because 3M offered no evidence that Abraham is qualified to offer the opinions described above (or any opinions in the areas in which he admitted he is not qualified, *see* Plaintiffs' Motion at 20-21), such opinions and conclusions should be excluded.

II. Abraham's Air Flow Study Is Irrelevant To Particle Movement

Everyone agrees CFD is a reliable methodology. That is true whether the CFD simulates air flow or particle flow. But 3M has failed to establish that one might divine the flow of ten micron particles in a turbulent OR from a CFD that merely simulates airflows.

3M has adduced no evidence to support its attorney argument that Abraham's airstream simulation can help the jury understand how the particles that carry bacteria move in an OR. That is critically important because this is not a case about air, it is a case about bacteria hitching a ride to the surgical site on particles. Everyone agrees that the

particles of interest are typically ten microns or larger. The operative *Daubert* analysis must be whether 3M has established that an airstream simulation can reliably predict flows of ten micron particles.

3M has not established evidence of reliability under any of *Daubert*'s non-exclusive factors: "(1) whether the theory or technique 'can be (and has been) tested'; (2) 'whether the theory or technique has been subjected to peer review and publication;' (3) 'the known or potential rate of error,' and (4) whether the theory has been generally accepted." *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996), quoting *Daubert*, 509 U.S. at 593-94.

As noted in Plaintiffs opening Motion, Dr. Abraham's report contained no data, experiments, or citations to publications that establish the reliability of extrapolating any particle flow, much less movement of the relevant ten micron or larger particles, from his air flow CFD. In fact, the term "particles" is nowhere in the description of Abraham's CFD analysis. Even after Plaintiffs raised the deficiency, 3M has offered no evidence that Abraham's theory, that particles of the relevant size follow airstreams, has been tested. 3M offered no evidence to show the known or potential rate of error that arises when one assumes that ten micron particles follow the airstreams in Abraham's CFD. 3M offered no evidence of general acceptance that airstreams are a reliable indicator of movement for ten micron particles.

The only "evidence" offered by Defendants (Def. Opp. at footnote 9) are four publications that the attorneys claim use CFD modeling of air streamlines to predict particle movement (none of which were cited in Abraham's expert disclosure). 3M

greatly overstates the application of those studies to the present dispute. For example, the Brohus study⁴ describes experiments with tracer gases and bacterial sampling, not CFD. Saarinen used CFD, but only to demonstrate the viability of the tool as a simulation alternative for trace gas and smoke studies.⁵ So neither of those publications offers any support for the contention that it is acceptable to predict particle movement, much less ten micron particle movement, by modeling airflows.

Srebric says only that “gaseous or particulate contaminants” are being simulated, but offers no disclosure of what size those contaminants are or what tools were used to conduct the simulations.⁶ There is no indication that Srebric modeled any particles in the range of those at issue in this case, and no claim that a model of sub-micron particles would apply to movement of larger particles. Srebric concludes by stating that the results will be inaccurate when “the point source is active and located in a complicated and hard-to-predict airflow field.”⁷ Srebric therefore does not support 3M’s contention that airstreams can be used as a proxy for contaminants generally, much less in the context of this dispute.

⁴ Brohus et al., *Influence of disturbances on bacteria level in an operating room*, 16 INDOOR AIR 356 (2008).

⁵ Saarinen et al., *Large Eddy Simulation of Air Escape through a Hospital Isolation Room Single Hinged Doorway—Validation by Using Tracer Gases and Simulated Smoke Videos*, 10(7) PLoS ONE e0130667 (2015).

⁶ Srebric et al., *CFD boundary conditions for contaminant dispersion, heat transfer and airflow simulations around human occupants in indoor environments*, 43 BUILDING & ENV’T 294 (2008).

⁷ *Id.* at 303.

3M misrepresents Tung entirely. Tung did not merely simulate airflows and then rely on those simulated airflows to assume where particles would move.⁸ Instead, Tung specified that they used CFD software that was “adopted to predict particle transport and distribution in ventilated rooms.”⁹ Tung further discloses that they used “Airpak,” an Ansys software module that enables a researcher to model contaminant distribution.¹⁰ Tung’s use of a specialized solver on top of CFD software that models airstreams strongly undercuts 3M’s assertion that airstreams alone are an acceptable predictor of particle movement.

None of the studies supplies a known error rate, nor has 3M supplied any known rate of error for Abraham’s prediction. Without a known (or even knowable) error rate, it is impossible to know whether Abraham’s assumption of particle movement is off by five hundred percent or five million percent. At most, Abraham has created an image in his mind about the movement of particles based on the computed airflows, but no one can know whether his mental image is reliable.

⁸ Tung et al., *Numerical study on the dispersion of airborne contaminants from an isolation room in the case of door opening*, 29 APPLIED THERMAL ENGINEERING 1544 (2009).

⁹ *Id.*

¹⁰ *Id.* at 1545. Airpak is a separate software module that runs on the Ansys Fluent CFD software. According to Ansys, Airpak is marketed in part for its ability to model contaminant concentrations in air streams See <http://www.figes.com.tr/english/ansys/product/airpak.php> (last visited Oct. 16, 2017). Tang’s use of a software package that specifically allowed contaminants to be modeled is entirely at odds with 3M’s assertion that Tang used airstreams as a proxy for particle movement.

Although he claimed to have simulated particles, he admitted that he assigned those particles zero mass and zero inertia.¹¹ He conceded that the size of the particle impacts its ability to follow an airstream, but could not describe what size particles would follow an airstream.¹²

Abraham's say-so is the only evidence supporting his guess of particle flow from airstreams. That is not enough. "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 at Committee Notes, quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995). There is no evidence to support extrapolation of Abraham's air flow simulation to the movement of bacteria-laden particles. This is a textbook example of an expert's "ipse dixit" effort to overcome the gap between data and the opinions offered. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Even if his simulation of airstreams were entirely accurate, he has "unjustifiably extrapolated from an accepted premise to an unfounded conclusion." Fed. R. Evid. 702 at Committee Notes. Without any evidence to establish any indicia of reliability, Abraham's divination of particle movement based on airstreams is pure speculation. "Speculative testimony should not be admitted." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2007). This Court should exclude Abraham's particle movement opinions and his irrelevant airflow simulations.

¹¹ DX2 (Abraham Dep. 227:17-228:7).

¹² *Id.* at 134:2-19.

III. Abraham's "Heat-Rises" Criticisms Are Not Rebuttal

Defendants concede that a rebuttal expert's role is to criticize Plaintiffs' expert's methodologies and point out potential flaws in their expert reports. Def's Response at 10, citing *Aviva Sports Inc. v. Fingerhut Direct Marketing*, 829 F. Supp. 2d 802, 835 (2011). The Eighth Circuit has explained that "The function of rebuttal testimony is to explain, repel, counteract or disprove **evidence of the adverse party.**" *United States v. Lamoreaux*, 422 F.3d 750, 755 (8th Cir. 2005) (emphasis added). But Abraham's "heat-rises" criticisms are unrelated to any "evidence of the adverse party." None of Plaintiffs experts relied on or discussed in any way the videos and commentary on that blog. As such, "heat-rises" testimony is not rebuttal testimony.

Nor should the Court countenance 3M's baseless assertion that Dr. Elghobashi "adopt[ed] Dr. Augustine's theories." Dr. Elghobashi is a respected engineer and academic. To the extent they believe he was influenced in any way by Augustine's blog or other positions, Defendants had ample opportunity to develop factual support for their Augustine conspiracy theory in Dr. Elghobashi's deposition. "Augustine" does not appear once in that entire deposition transcript. They did not ask a single question that would allow them to make that assertion in good faith. The Court should reject their unfounded attempt to besmirch Dr. Elghobashi and his analysis via criticism of material upon which he did not rely. It is not "rebuttal" evidence and has no place in this litigation.

IV. Abraham's Measurements Are Untestable and Therefore Unreliable

Even if his experience with this newly invented middle-ground between low-speed flows and high-speed flows qualified Abraham to conduct a CFD experiment, Abraham

admitted in deposition that various key boundary conditions are not disclosed – elements even Abraham admits are essential in order for Plaintiffs to explore the accuracy and reliability of his measurement tests.¹³

The two, solitary “air velocity” sentences quoted by 3M on page 7 of their brief and the results in Abraham’s report are a far cry from disclosing a reliable methodology for air velocity or temperatures. Abraham repeatedly admitted in deposition that his report disclosed no equations or other data illustrating the methodology underlying his CFD, or even information sufficient to determine whether the data he produced was representative of the CFD results.¹⁴

The disclosure of a methodology is necessary for 3M to establish that their witness complied with *Daubert* and Rule 702. CFD is surely a reliable tool, but without reasonable access to underlying data it is impossible to know if the CFD results were cherry-picked. The only basis anyone has to determine whether the simulation reached a “quasi steady state” is Abraham’s visual comparison of two results, only one of which has been produced.

The complete absence of any disclosed methodology leaves Plaintiffs without a basis to discover (1) whether the methodology itself was reliable; or (2) the extent to which Abraham deviated from that methodology.¹⁵ As a practical matter, Abraham’s

¹³ See DX2 (Abraham Dep. 71:9; 68:3; 251:17).

¹⁴ See *id.*

¹⁵ Even if a methodology is reliable, failure to adhere to that methodology is grounds for exclusion. See *Presley v. Lakewood Eng’g and Mfg Co.*, 553 F.3d 638, 645 (8th Cir. 2009) (excluding expert for failing to follow the NFPA 921 fire investigation standard);

testing fails one or both of those prongs. He admitted a host of irregularities in his testing, and confessed he deleted files that would reveal details he can no longer recall, including changing the various boundary conditions and time-step increments at undisclosed points during the CFD.¹⁶ It is not even clear that the simulation images in his report resulted from the single simulation data file he produced to Plaintiffs.

3M now argues that Plaintiffs had the data file for months and should have requested additional data. But 3M has reversed the burden, Rule 26(a)(2)(B)(i) requires an expert disclosure to set forth “a complete statement of all opinions … *and the basis and reasons for them.*” (Emphasis added). Moreover, Abraham had the equations readily available—he included them in a paper that was recently published. “What is required is that when experts ‘testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work.’” *Group Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F. 3d 753, 760 (8th Cir. 2003) (*quoting Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)). It is beyond question that Abraham failed to adhere to the same standards as he applies in his academic work.

Defendants, as the party offering Abraham’s opinion, must establish that Abraham used a reliable methodology and followed the requirements of that methodology. By failing to disclose the specific methodology, including the boundary conditions and time-

see also Russell v. Whirlpool Corp., 702 F.3d 450 (8th. Cir. 2012) (noting that if an expert had used NFPA 921 fire investigation protocol but had failed to apply it reliably, he would have been excluded).

¹⁶ DX2 (Abraham Dep. 321:13).

steps used in his CFD, Abraham's testing opinions necessarily fail to meet the requirements of Rule 702.

CONCLUSION

Abraham offered wide-ranging opinions and conclusions that far exceed his area of expertise: heat transfer. They have produced no evidence that his air flow simulation can be extrapolated to predict the flow of relevant particles. Without that evidence, Abraham has no basis upon which to offer his conclusions about movement of bacteria in the OR.

In addition, Abraham's report and production of materials failed to disclose any information by which 3M could establish that Abraham adopted a reliable methodology and applied it reliably. At deposition, Abraham confessed he deleted the files that would have allowed Plaintiffs the opportunity to test the veracity of the CFD and Abraham's proffered conclusions. Because Defendants cannot show that Abraham used reliable principles to reach his opinions, his testimony should be excluded in its entirety.

Respectfully submitted,

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